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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/588,637	01/19/1996	ALAN G. BARBOUR	454312-2420	6046

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/07/2002

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 28

Application Number: 08/588,637

Filing Date: 19 January 1996

Appellant(s): Barbour et al

Thomas J. Kowalski

For Appellant

Art Unit: 1645

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4 March 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

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The rejection of claims 1-4, 6-10, 12, and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512 in view of Bergstrom et al (U.S. Patent No. 5,523,089) is hereby withdrawn.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-4, 6-10, 12, and 13 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,688,512	BERGSTROM et al	11-1997
5,523,089	BERGSTROM et al	6-1996
Cohen, S.N.	"Immunization", in, Basic and Clinical Immunology, 3rd Ed., H.H. Fudenberg, D.P. Stites, J.L. Caldwell, J.V. Wells, eds., Lange Medical Publications, Los Altos, CA. (1980), pp. 708-721.	

(10) *Grounds of Rejection*

The following grounds of rejection are applicable to the appealed claims:

Claims 1-4, 6-10, 12, and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512 in view of Cohen.

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The independent claim 1 is drawn to a method for inducing an immunological response in a mammalian host susceptible to Lyme disease or *Borrelia burgdorferi* infection comprising mucosally administering a composition comprising substantially pure outer surface protein A (OspA) and a carrier or diluent. The dependent claims 2-4, 6-10, 12, and 13 are further drawn to the type of OspA (recombinant, lipidated), how it is administered (orally or generally mucosal), and the choice of a carrier/diluent.

Claim 2 of U.S. Patent No. 5,688,512 depends from independent claim 1. Therefore, claim 2 is drawn to "A method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme disease comprising administering a vaccine comprising substantially pure OspA, and an immunologically acceptable carrier or vehicle to the animal or human in an amount effective for inducing the protective immunological response."

The recitation in claim 2 of U.S. Pat. No. 5,688,512 of "comprising administering a vaccine comprising substantially pure OspA" encompasses any route of administration, e.g., mucosal, intramuscular, subcutaneous, etc. Mucosally administering the composition is but one type of administration. Cohen is a chapter from a textbook, utilized by the medical teaching profession, to discuss various vaccines and various routes of administration with mucosal administration merely one route of several.

Thus, since the field of immunization as evidenced by the Cohen reference recognized mucosal administration of vaccines as but one of several appropriate routes of administration, it would have been obvious to one of ordinary skill in the art at the time the invention was made that mucosal/oral administration of the claimed composition was an obvious variant of the many routes of administration available.

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(11) Response to Argument

Appellants argue that nothing in claim 2 of U.S. Pat. No. 5,688,512 or Cohen directs the skilled artisan to mucosally or orally administer the OspA of the instant claims and that neither reference provides motivation to modify the subject matter thereof to arrive at the present invention. Claim 2 administration can be by any route, but no particular route of administration is specified. Therefore, there is nothing in the disclosure of claim 2 that teaches or suggest the particular mucosal administration. Appellants argue that the Examiner failed to demonstrate why one should select oral or mucosal administration from all of the ways one can administer OspA based only upon the text of claim 2.

As appellants admit, claim 2 is directed to administration of OspA by any route, i.e., encompassing all routes, two of which are oral and mucosal. Cohen teaches various administration routes for effective immune response induction depending upon the organism being used, including mucosal/oral administration. Thus, one of skill in the art would have been motivated to modify the subject matter of claim 2, i.e., administration of OspA by **any/all** route(s), to utilize one of the effective routes taught by Cohen, either mucosal or oral.

Appellants argue that claim 2 of U.S. Pat. No. 5,688,512 requires protective immunity whereas the instantly rejected claim may result in protective immunity, but need not result in protective immunity.

As appellants admit in their argument, the scope of both the instant claims and claim 2 comprises protective immunity. Thus, the instant claims are obvious variants of claim 2.

Appellants argue that claim 2 of U.S. Pat. No. 5,688,512 does not teach or suggest administration of lipidated OspA as recited in instant claims 2-4, 6, and 8-10, but only generic OspA.

Appellants argue that neither claim 2 of U.S. Pat. No. 5,688,512 nor Cohen teach or suggest the

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mucosal administration of OspA in solution, suspension, emulsion, syrup, elixir, capsule, tablet, hard-candy-like preparation, or a solid food item.

According to M.P.E.P. §804, section II.B.1, paragraphs 6 and 7, determination of whether an invention of defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. However, the specification can be utilized as a dictionary in order to determine the meaning of a term in the patent. In addition, those portions of the specification which provide support for the patent claim may also be examined and considered when determining whether a claim in an application defines an obvious variation of an invention claimed in the patent.

Thus, to determine the support and definition concerning the recitation in claim 2 of U.S. Pat. No. 5,688,512 for "administering the vaccine of claim 1 to the animal or human in an amount effective for inducing the proective immunological response", one utilizes the specification. Specifically, column 18, lines 30-38 recite:

"any immunization route which may be contemplated or shown to produce an appropriate immune response can be employed in accordance with the principle of the present invention. Suitable administration forms of the vaccine of the invention are oral administration forms, e.g. tablets, granules or capsules, subcutaneous, intracutaneous or intramuscular administration forms or forms suitable for nasal or rectal administration."

Thus, the definition and support for patentability of claim 2 encompasses oral and mucosal (rectal) administration.

Likewise, patented claim 2 encompasses the administration of **any/all** forms of OspA of which lipidated OspA is but one obvious variant encompassed by the scope of the claims.

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Claim 2 is directed to administration of OspA in any "acceptable carrier or vehicle" which encompasses **any/all** forms of administration, including solutions, suspensions, emulsions, syrups, elixirs, capsules, tablets, hard-candy-like preparations, or solid food items. The choice of a particular carrier or vehicle would be an obvious variant for one skilled in the art of immunization based upon that skilled artisan's experience in the field.

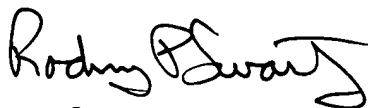
Thus, for the reasons put forth above, appellants' arguments that each of the rejected claims is directed to a subgenus or species of OspA, route of administration, level of immunization, or carriers, distinct from claim 2 of U.S. Pat. No. 5,688,512, are not found persuasive and it is believed that the rejections should be sustained.

Respectfully submitted,

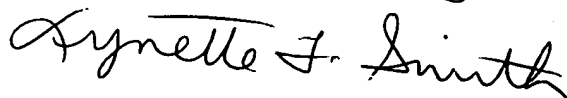
July 30, 2002

Conferees

Rodney P. Swartz, Ph.D., Primary Examiner



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